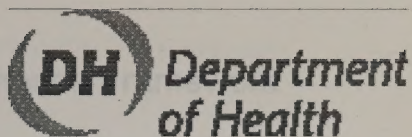


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Research Governance Implementation Plan

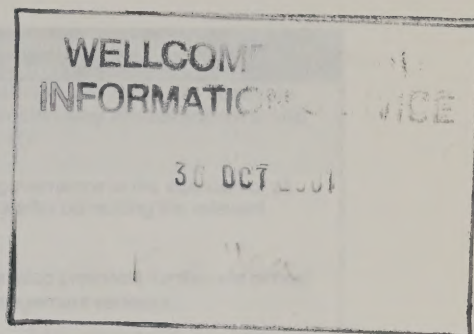
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Department of Health Research Governance Framework for Health and Social Care:

Implementation Plan



Section 1 Introduction

- 1.1 The Department of Health *Research Governance Framework for Health and Social Care* ([click here](#) to download) gave guidance on good practice in the collaboration between researchers, health and social care teams and their employers and funders. The *Research Governance Framework* covers all research activities undertaken in areas for which the Secretary of State has responsibility.
- 1.2 The *Research Governance Framework* is intended to sustain a research culture that promotes excellence, with visible research leadership and expert management to help researchers, clinicians and managers apply standards correctly. This implementation plan sets out action required to ensure that organisations in health and social care comply with the *Research Governance Framework*. Key targets and milestones are summarised in the table in section 2.
- 1.3 The rest of the plan details actions for care organisations in the NHS (section 3); for primary care (section 4); and for social care (section 5). Action required of bodies that will act as research sponsor is in section 6. The plan relies on other research funders, and on universities, to take the actions outlined in sections 7 and 8. Section 9 concerns monitoring, risk management and controls assurance.
- 1.4 The full development of robust agreements and systems for research governance will take time. Meanwhile, those concerned with R&D in health and social care must continue to use their best endeavours to avoid the risks for participants that the *Research Governance Framework* is designed to deal with.
- 1.5 The implementation plan groups research governance issues into:
 - ☐ legal requirements;
 - ☐ systems for urgent attention;
 - ☐ systems development:
 - ☐ systems development by March 2003;
 - ☐ capacity building by March 2004.

Section 2 Target dates for research governance in health and social care

Target dates and milestones for compliance with the Department of Health Research Governance Framework for Health and Social Care	
By December 2001 (paragraph 3.8)	All research active NHS care organisations have access to adequate systems for notification of R&D and for checking ethical approval and informed consent (<i>indicators 1, 10 and 11</i>).
In 2002 (paragraph 4.1)	DH draws the requirements of research governance to the attention of all research active independent practitioners after consulting the relevant professional bodies and Royal Colleges.
During 2002 (paragraph 4.3)	DH works with Primary Care Trusts to develop protocols for the role of host for shared research governance and management services.
By March 2002 (paragraph 6.3)	DH arranges for a baseline assessment of the way it complies with the responsibilities of research sponsor and establish an internal implementation plan.
From April 2002 (paragraph 7.2)	A funding body makes clear, for each grant it awards for R&D in the NHS, whether it will itself act as research sponsor or whether it expects another organisation to agree to do so.
July 2002 (paragraph 3.9)	Each research active NHS care organisation has a local research governance implementation plan.
December 2002 (paragraph 5.2)	Implementation plan for research governance in social care is published.
March 2003 (paragraph 3.11)	Research active NHS care organisations comply with all the requirements in paragraph 3.10 (<i>indicators 2, 3, 4, 5, 6, 8, 12, 14, 16, 20</i>).
March 2003 (paragraph 3.12)	All researchers not employed by the NHS hold a NHS honorary contract that includes research governance procedures and responsibilities if they are to interact with individuals in a way that has a direct bearing on the quality of health care.
April 2003 (paragraph 3.9)	Research active NHS care organisations report progress.
April 2003 (paragraph 6.5)	No research with human participants, their organs, tissue or data may begin or continue in the NHS until a research sponsor has confirmed it accepts responsibility.
By April 2003 (paragraph 4.4)	There is a national network of Primary Care Trusts ready to act as host for shared research governance and management capacity.
April 2003 (paragraph 6.6)	The national network of PCTs begins to stand as research sponsor for R&D in health and social care where it is inappropriate for another organisation to do so.
By March 2004 (paragraph 4.6)	All primary care practices that lead non-commercial R&D are accredited.
March 2004 (paragraph 3.9)	All research active NHS care organisations comply with the <i>Research Governance Framework</i> , unless there are well-documented reasons for a longer timetable.
April 2004	Research active NHS care organisations report progress.
By May 2004 (paragraph 3.5)	Member States bring the EU Directive on Good Practice in Clinical Trials into force in domestic law.

Section 3 Action for NHS care organisations

- 3.1 The Department of Health seeks to promote effective and cost-effective arrangements for research governance across health and social care. It expects care organisations to participate in robust arrangements, often operated jointly with others. The responsibilities in the *Research Governance Framework* should be allocated by explicit agreement to those able to accept them. An organisation that accepts accountability may not devolve it to someone else, but will usually share the mechanisms for ensuring compliance.
- 3.2 In a baseline assessment of NHS care organisations in May 2001 ([click here](#) for details), 572 NHS respondents declared they are research active. The Department of Health will make available to research ethics committees a list of NHS care organisations declared to be research active.
- 3.3 The rest of this section of the plan describes action to follow up the baseline assessment. (The indicators listed are those in the baseline assessment.)
- 3.4 Three indicators (17, 22 and 25) are **legal requirements** now, and in standing NHS procedures. Ensuring compliance is for general performance management:
- ❑ Systems to ensure researchers are aware of the Data Protection Act and other legal provisions and guidance on handling information;
 - ❑ Systems to ensure financial probity;
 - ❑ Arrangements to make researchers aware of their responsibilities under the Health and Safety Act both in respect of themselves and of other participants.
- 3.5 By May 2004, Member States are required to bring into force in domestic law EU Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medical products for human use. The *Research Governance Framework* is intended to be consistent with the Directive. Aspects of the *Framework* will become legal requirements for clinical trials.
- 3.6 Three indicators (1, 10 and 11) were signalled for **urgent attention**:
- ❑ systems to ensure an appropriate member of staff is notified of, and has approved, all research in the care organisation;
 - ❑ systems to ensure all ongoing research has ethics committee approval;
 - ❑ arrangements to ensure someone acceptable is responsible for making sure that informed consent and procedures in the protocol approved by the ethics committee are being adhered to.
- 3.7 90 non-compliant NHS care organisations were asked to prepare a recovery plan. 72 of these reported they would be compliant in these areas by September 2001.
- 3.8 *Target: Research active NHS care organisations will have access by December 2001 to adequate systems for notification and for checking ethical approval and informed consent.* For any organisation that does not, its Chief Executive should decide, taking account of the risks, whether or not R&D should continue until it does have access to the systems required, and report to the Department of Health by March 2002.

- 3.9 *Target: By July 2002 each research active NHS care organisation will have a local implementation plan.* It should set out steps towards compliance with the indicators in paragraphs 3.6, 3.10 and 3.13. It should reflect the current level of compliance and the risks to individual participants in research. NHS care organisations should aim for compliance in all areas by March 2004 unless there are well-documented reasons for a longer timetable. Plans should be proportionate to the risk to individuals participating in R&D to whom the organisation has a duty of care. *NHS care organisations will report progress in April 2003 and April 2004.*
- 3.10 These indicators (2, 3, 4, 5, 6, 8, 12, 14, 16, 20) call for **systems development**
- ❑ documented agreements with research partners to allocate responsibilities;
 - ❑ system to ensure all staff are aware of the *Research Governance Framework*;
 - ❑ links between research governance and clinical governance systems;
 - ❑ arrangements for monitoring research projects;
 - ❑ system to record any adverse events;
 - ❑ making compliance with the *Research Governance Framework* a term of all relevant employment contracts;
 - ❑ arrangements to issue NHS honorary contracts to non-NHS researchers;
 - ❑ systems to ensure all research in your organisation has a nominated sponsor;
 - ❑ systems to ensure all research is subject to independent expert review through accepted scientific and professional channels;
 - ❑ systems to have all research by students approved by your organisation;
 - ❑ appropriate written agreements with research sponsors and other funders to cover all funded research in your organisation.
- 3.11 *Target: Research active care organisations will comply in all the above areas by March 2003.*
- 3.12 The *Research Governance Framework* recommends framework agreements between organisations that collaborate on a range of research work. The NHS R&D Management Forum, the Medical Research Council (MRC) and the Department of Health will co-ordinate discussions to develop model framework agreements by April 2002. NHS bodies, universities and funders are encouraged to contribute. Sir Brian Follett's review of appraisal, disciplinary and reporting arrangements for senior NHS and university staff with academic and clinical duties ([click here](#) for details) recommends better joint supervision of clinical academic staff. *Target: By March 2003, all researchers not employed by the NHS will hold a NHS honorary contract that includes research governance procedures and responsibilities if they are to interact with individuals in a way that has a direct bearing on the quality of care.*
- 3.13 To promote a quality research culture, **capacity building** may be needed in these areas (indicators 7, 15, 18, 19, 21, 23, 24):
- ❑ systems to detect and deal with research misconduct and fraud;
 - ❑ involvement of consumers in the development and execution of research projects, where appropriate;
 - ❑ systems to inform service users and members of the public about research being undertaken in your organisation;
 - ❑ access to systems for costing and financial management of research;
 - ❑ arrangements to ensure all research is appropriately disseminated;
 - ❑ systems for the identification of research-based intellectual property;
 - ❑ access to systems, where appropriate, for ownership, exploitation and income from intellectual property.

- 3.14 Research active NHS care organisations should have robust arrangements in all these areas by March 2004. See also section 6: research sponsors.
- 3.15 The Department of Health will work with NHS, university and other stakeholders to develop and issue guidance on good practice. It will consider with the NHS R&D Management Forum what development activities to support.

Section 4 Primary and Community Care

- 4.1 In the baseline assessment 78 Primary Care Trusts (PCTs), 36 Primary Care Groups (PCGs) and 83 General Practitioners (GPs) declared they were research active. These included all those receiving NHS R&D funding. In 2002 the Department of Health will draw the requirements of research governance to the attention of all research active independent practitioners after consulting the relevant professional bodies and Royal Colleges.
- 4.2 PCTs will become the lead NHS organisations in assessing need, planning and securing health services and improving health in their localities. They will also provide most community services and develop primary care services. They will have responsibility for the services provided by all family health service professionals from April 2002. Teaching PCTs will be established in 2002/03 and 2003/04 ([click here](#) for details).
- 4.3 New PCTs will need time and support to establish R&D systems. By October 2002 the Department of Health will invite proposals from those PCTs best placed to be the host for research governance and management services shared with other PCTs and with appropriate collaborations of research active organisations and individuals in health and social care. During 2002 the Department will work with selected PCTs to develop protocols for this role.
- 4.4 *Target: By April 2003 there will be a national network of PCTs ready to act as host for shared research governance and management capacity.*
- 4.5 The Department of Health will work with the Royal College of General Practitioners and others to introduce accreditation for research active primary care practices. The Department will develop arrangements with the Medical Research Council through the General Practice Research Framework (GPRF) to support sites in primary care that collaborate occasionally in R&D.
- 4.6 *Target: By March 2004 all primary care practices that lead non-commercial R&D will be accredited.* All primary care practices collaborating in R&D will do so in association with accredited practices or through the GPRF.

Section 5 Social Care

- 5.1 The Department of Health will consult relevant stakeholders before arranging for a baseline assessment of organisations active in social care research that relates to the responsibilities of the Secretary of State for Health.
- 5.2 *Target: An implementation plan for research governance in social care will be published by December 2002.*

Section 6 Research Sponsors

- 6.1 All R&D in the NHS is subject to the *Research Governance Framework* for Health and Social Care and must in future have a research sponsor that accepts the responsibilities set out in section 3.8 of the *Framework*. Research sponsors will normally expect assurances from employers of researchers and of care teams that they accept the usual employers' liabilities.
- 6.2 The Department of Health will arrange to maintain a list of recognised sponsors of health and social care research that have declared they will accept these responsibilities. External funders may declare at any time. ([Click here](#) for details).
- 6.3 The Department of Health will arrange for a baseline assessment of the way it complies with the responsibilities of research sponsor itself, and establish an internal implementation plan by March 2002.
- 6.4 In 2002 the Department will give detailed guidance on the role of NHS organisations acting as research sponsor, and determine which organisations are to act as sponsor for agreed programmes of collaborative R&D within the NHS Priorities and Needs R&D funding system (indicator 13).
- 6.5 Care organisations will then consider whether any R&D under way that affects their duty of care should be suspended until a research sponsor has confirmed it accepts responsibility. *Target: From April 2003 no research with human participants, their organs, tissue or data, may begin or continue in the NHS until a research sponsor has confirmed it accepts responsibility.*
- 6.6 *Target: from April 2003 PCTs that are host to shared research governance and management capacity (paragraph 4.4) will begin to stand as research sponsor for R&D in health and social care where it is inappropriate for another organisation to do so.*

Section 7 Research Funders

- 7.1 Research governance requires clear understandings between research funders, the employers of the principal investigator and research teams and the employers of the care professional and the care team responsible for the care of participants in research.
- 7.2 The Department of Health *Guide to Collaboration in R&D between the NHS and other research funders* ([click here](#)) summarises the ways in which non-NHS bodies and the NHS may collaborate. External research funders are expected to manage their funding for health and social care research according to the principles of the *Research Governance Framework*. From April 2002 a funder will be expected to make clear, for each grant it awards, whether it will itself act as sponsor for research it funds, or whether it expects another organisation to agree to do so.
- 7.3 The Department will extend the *Guide* to cover industry-funded research.

Section 8 Universities

- 8.1 Strengthening research governance in health and social care implies close collaboration between universities and the NHS. The NHS will rely on universities to:
 - ❑ support the NHS in promoting a quality research culture that extends to every aspect of health and social care research;
 - ❑ participate in framework agreements that allocate research governance responsibilities to those equipped to accept them;
 - ❑ work closely with care organisations to ensure high standards of joint supervision for research teams and for research active care teams, and maintain systems to meet these responsibilities ;
 - ❑ take part in NHS/academic groupings that can deliver collaborative programmes of R&D designed to meet the needs of health and social care;
 - ❑ work closely with the NHS to develop information systems that support high standards of research governance and clinical governance.
- 8.2 When brought into force in domestic law, the EU Directive on good clinical practice in clinical trials (paragraph 3.5 above) will apply to work undertaken by university researchers as well as others. Universities should work with their NHS partners to develop joint quality systems.
- 8.3 Universities and research active NHS care organisations are expected to make arrangements for honorary contracts, independent expert review and appropriate dissemination of findings in the context of Sir Brian Follett's recommendations about appraisal, disciplinary and reporting arrangements for senior NHS and university staff with clinical and academic duties (paragraph 3.12 above).

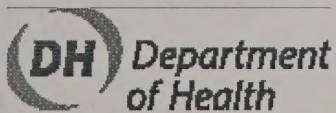
- 8.4 The NHS will welcome collaborative research that has no external research sponsor in the context of an agreed collaborative programme within NHS Priorities and Needs R&D Funding. These programmes will comprise R&D for which a NHS sponsor is willing and able to accept responsibility. In this context, the NHS will welcome co-funding from charitable and other funders of research.

Section 9 Monitoring, risk management and controls assurance

- 9.1 There are established mechanisms and bodies responsible for monitoring standards of governance in the domains that comprise research governance. The Department of Health will work with its partners in 2002 to establish a coherent system to monitor research governance and address shortcomings. It will work with and through existing structures. It will consult on creating a new unit to monitor the work of research sponsors in health and social care.
- 9.2 The *Research Governance Framework* brings together requirements for systems, processes and arrangements to manage a variety of risks. It calls for prior agreement on the allocation of these responsibilities. It requires the sponsor to ensure that there are proportionate arrangements and that scientific judgements in relation to these responsibilities are based on independent and expert advice.
- 9.3 In planning for the EU Directive on the implementation of good clinical practice in the conduct of clinical trials on medical products for human use (see paragraph 3.5) care organisations and their research partners should develop quality systems for such work, including written procedures and staff training. Monitoring and/or audit arrangements should be based upon documented risk assessments of trials.
- 9.4 Controls assurance is fundamental to governance in the NHS. HSC 199/123 – *Controls Assurance Statements 1999/2000: Risk management and organisational controls*, identifies the system of internal control in the NHS comprising three sub-systems: financial, organisational and clinical controls. Through 2002 the Department of Health will, in consultation with stakeholders, define an appropriate controls assurance system for research governance.
- 9.5 Strategic Health Authorities when constituted will ensure all organisations work together to deliver modernised patient centred services and the NHS Plan. Their duties will include performance management and performance improvement.
- 9.6 Concern over research misconduct and fraud continues. In 2002 the Department of Health will work with others, including other government departments and professional bodies, to develop a joint approach based on the responsibilities of the stakeholders concerned with research in health and social care.

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